

**REMARKS**

Claims 51, 53, 55-56, 71-72, 75, 77-78, 84, 86, 88-89, 95-98, 100, 102-104, 106, 108-112, 114 and 116-121 were pending in the application. Claims 51, 53, 71, 75, 84, 86, 95, 100, 104, 106, 112 and 114 have been amended. Accordingly, claims 51, 53, 55-56, 71-72, 75, 77-78, 84, 86, 88-89, 95-98, 100, 102-104, 106, 108-112, 114 and 116-121 will remain pending following entry of this amendment.

***Objection to the Specification***

The Examiner has required under 37 CFR 1.82(d) that sequence identification numbers be assigned to all sequences presented in the specification. Accordingly, the specification has been amended herein to assign sequence identification numbers to the two oligonucleotide primer sequences presented at page 59 of the specification as filed, and a replacement sequence listing is submitted herewith. No new matter has been added by way of this amendment.

***Rejection of Claims 53, 75, 86, 100, 106 and 114 Under 35 U.S.C. § 112, First Paragraph***

The Examiner has maintained his previous rejection of claims 53, 75, 86, 100, 106 and 114 under 35 U.S.C. § 112, first paragraph, as lacking written description. The Examiner specifically alleges that “recitation of the term ‘functional’ fragments is not supported by an adequate written description in the specification as filed.

Applicants continue to find this rejection improper for reasons cited in their Amendments filed February 24, 2005, September 6, 2005 and December 1, 2005. Indeed, Applicants submit that both the specification and claims 53, 75, 86, 100, 106 and 114 make clear that a functional soluble human LT $\beta$ R agent of the invention is one that contains at least one ligand binding domain of human LT $\beta$ R (refer to the present specification, at least at page 32, lines 23-27). However, solely in the interest of expediting prosecution of the instant application, claims 53, 75, 86, 100, 106 and 114 have been amended to specify “SEQ ID NO: 1, or a functional fragment thereof ***encoding an LT $\beta$ R ligand binding domain*** (emphasis added).” In view of the

Applicants' prior arguments and the amendment of claims 53, 75, 86, 100, 106 and 114 herein, Applicants request that this rejection be reconsidered and withdrawn.

***Rejection of Claims 51, 53, 55-56, 71-72, 75, 77-78, 84, 86, 88-89, 95-98, 100, 102-104, 106, 108-112, 114 and 116-121 Under 35 U.S.C. § 112, Second Paragraph***

The Examiner has newly rejected claims 51, 53, 55-56, 71-72, 75, 77-78, 84, 86, 88-89, 95-98, 100, 102-104, 106, 108-112, 114 and 116-121 under 35 U.S.C. § 112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner states that "all claims are deemed indefinite because it is unclear as to whether applicant intends for the LT ligand to be fused to the heterologous protein domain or whether the LT- $\beta$  R is to be fused to the heterologous domain." Applicants traverse this rejection, especially as applied to claims 119-121, that specify "a pharmaceutical composition comprising a soluble human lymphotoxin-beta receptor (LT $\beta$ R) comprising SEQ ID NO: 1 fused to a human IgG1 Fc domain and a pharmaceutically acceptable carrier." Applicants respectfully submit that one of ordinary skill in the art would recognize the pending claims to concern fusion of soluble human lymphotoxin-beta receptor (LT $\beta$ R) sequence to a heterologous protein domain. However, solely in the interest of expediting prosecution of the current invention, Applicants have amended claims 51, 71, 84, 95, 104 and 112 to recite "a soluble human lymphotoxin- $\beta$  receptor (LT $\beta$ R) fused to one or more heterologous protein domains . . . ." Applicants respectfully submit that the preceding amendment clarifies that claims 51, 71, 84, 95, 104 and 112 require fusion of soluble human lymphotoxin-beta receptor (LT $\beta$ R) sequence to the heterologous protein domain.

The Examiner has also rejected claim 51 under 35 U.S.C. § 112 for lack of antecedent basis for the term "the mammal" in line 2 of the claim. Applicants have herein amended claim 51 to recite "the human" in line 2 of this claim, rendering the present objection moot.

In view of the present amendments to claims 51, 71, 84, 95, 104 and 112, Applicants respectfully request that this rejection be reconsidered and withdrawn.

***Rejection of Claims 51, 53, 55-56, 71-72, 75, 77-78, 84, 86, 88-89, 95-98, 100, 102-104, 106, 108-112, 114 and 116-121 Under 35 U.S.C. § 112, First Paragraph***

The Examiner has newly rejected claims 51, 53, 55-56, 71-72, 75, 77-78, 84, 86, 88-89, 95-98, 100, 102-104, 106, 108-112, 114 and 116-121 under 35 U.S.C. § 112, first paragraph, as lacking written description. The Examiner specifically alleges that “[t]he specification as filed does not support a fusion protein comprising a surface LT ligand conjugated or fused to a heterologous protein domain as claimed. Applicant may overcome this rejection by *[sic]* indicating that the LT-β R is fused to the heterologous domain.” Applicants traverse this rejection in view of the present amendments to claims 51, 71, 84, 95, 104 and 112, that specify fusion of LT-β R to the heterologous domain. In view of these amendments, Applicants respectfully request that this rejection be reconsidered and withdrawn.

***Provisional Rejection of Claims 51, 53, 55-56, 71-72, 75, 77-78, 84, 86, 88-89, 95-98, 100, 102-104, 106, 108-112, 114 and 116-121 Under the Judicially Created Doctrine of Obviousness-Type Double Patenting***

The Examiner has provisionally rejected claims 51, 53, 55-56, 71-72, 75, 77-78, 84, 86, 88-89, 95-98, 100, 102-104, 106, 108-112, 114 and 116-121 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 55-56, 59-62, and 64 of co-pending Application No. 10/003,211. In particular, the Examiner is of the opinion that

[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because SLE is an autoimmune disease associated humoral immune responses. Therefore, the claims of the co-pending application are deemed to be a species encompassed within the broad claims of inhibiting a humoral immune response, or treating an antibody-mediated disease as claimed. Moreover, the claims of the instant application represents a genus of immune responses, of which include autoimmune diseases as claimed in co-pending application 10/03,211. As such, a species anticipates a genus.

While in no way admitting that claims 51, 53, 55-56, 71-72, 75, 77-78, 84, 86, 88-89, 95-98, 100, 102-104, 106, 108-112, 114 and 116-121 of the present application are obvious over claims 55-56, 59-62, and 64 of co-pending Application No. 10/003,211, upon allowance of the ‘211

application Applicants will consider submitting a terminal disclaimer in that application in compliance with 37 C.F.R. 1.321(b) and (c), if appropriate, which will obviate this rejection.

**SUMMARY**

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

By 

Amy E. Mandragouras

Registration No.: 36,207

LAHIVE & COCKFIELD, LLP

28 State Street

Boston, Massachusetts 02109

(617) 227-7400

(617) 742-4214 (Fax)

Attorney/Agent For Applicant